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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,793	06/13/2000	Jiangchun Xu	210121.427C15	5630

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/593,793	XU ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,22,61 and 63-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19, 22, 61, 63-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-18, 20-21, 23-60 and 62 have been cancelled.

Claim 19, 22, 61, 63 and 64 have been amended.

2. Claims 19, 22, 61 and 63-65 are pending and under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This Office Action contains New Grounds of Rejections.

Objections/Rejections Withdrawn

5. The objection to the disclosure (item no. 3) for not containing the updated status for all U.S. application numbers in the priority statement on the first line of the specification is withdrawn in view of the abstract filed 7/19/2004.

6. The objections to the specification (item nos. 4a-c) for not containing the patent number for USSN 09/020,956 (item no. 4a) and for not containing the updated status for USSN 08/700,014 as "now abandoned" (item no. 4b) and for containing an embedded hyperlink (item no. 4c) are withdrawn in view of the amendments filed 7/19/2004.

7. The rejections of claims 64-65 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the Applicant's arguments and amendments to the claims.

8. The rejection of claims 19, 20, 22 and 61-65 under 35 U.S.C. 112, first paragraph, written description, as containing subject matter, which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicant's arguments and amendments to the claims.

9. The rejection of claims 19, 20, 22, 61 and 63-65 under 35 U.S.C. 112, first paragraph, enablement, as the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims is withdrawn in view of Applicant's arguments and amendments to the claims.

10. The rejection of claims 19, 22, 61, and 63 under 35 U.S.C. 103(a) as being unpatentable over Xu et al as evidenced by the instant disclosure in view of Hauser et al and Ladd et al is withdrawn in view of the Assignment information filed 7/19/2004 establishing common ownership of the subject matter of U.S. Patent 6,261,562 (Xu et al) and the instantly claimed invention.

Response to Arguments

11. The Examiner acknowledges that Applicant has identified that instantly claimed residues 367-375 of SEQ ID NO:113 and the disclosure of the epitope sequence corresponding to these residues was first made by Applicant's in USSN 09/232,149, filed 1/15/99, now U.S. Patent 6,465,611. In view of Applicant's amendments to the CROSS REFERENCE TO RELATED APPLICATIONS on the first line of the specification 09/232,149 is the earliest

application to which priority is now claimed. The priority date of the instant claims is deemed to be that of USSN 09/232,149, i.e., 1/15/1999.

12. The rejection of claims 19, 22, 61 and 63 under 35 U.S.C. 103(a) as being unpatentable over Billing-Mendel et al in view of Hauser et al and Ladd et al is MAINTAINED.

The response filed 7/19/2004 has been carefully considered, but is deemed not to be persuasive. The response argues that none of the references, Billing-Mendel et al, Hauser et al and Ladd et al teach that a polypeptide of SEQ ID NO:113 represents a human T-cell immunogen, or that residues 367-375 of SEQ ID NO:113 correspond to a human T-cell epitope. The response also argues that it could not have been obvious, absent prior knowledge of the T-cell immunogenicity and T-cell epitope of residues 367-375 of SEQ ID NO:113, which did not exist prior to applicant's disclosure, to combine the currently claimed polypeptide of SEQ ID NO:113 with an immunostimulant which induces a predominantly Th1 type response. In response to this argument, Applicant is reminded that artisans of ordinary skill may not recognize the characteristics or functioning of the prior art... however, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Further, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable.

Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Accordingly, since Billing-Mendel et al teach a polypeptide sharing 100% amino acid identity with residues 299-529 of SEQ ID NO:113 (i.e., polypeptide comprising amino acid residues 367-375 of SEQ ID NO:113), the polypeptide taught by Billing-Mendel et al comprises any and all properties instantly claimed (e.g., residues 367-375 correspond to a human T-cell epitope and a polypeptide of SEQ ID NO:113 is a human T cell immunogen). Additionally, Billing-Mendel teach that SEQ ID NO:36, which is identical to residues 299-529 of SEQ ID NO:113 (i.e., is a polypeptide wherein the polypeptide comprises at least amino acid residues 367-375 of SEQ ID NO:113) is expressed in prostate cancer tissue and Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin (see columns 16-17) and Hauser et al teach that 3-O-deacylated monophosphoryl lipid A (MPL) in combination with an antigen is a potent inducer of Th1 cells and is important in the development of therapeutic vaccines (see column 18). Therefore, the skilled artisan would have been motivated an had a reasonable expectation of success at the time the invention was made to combine saponin or MPL to the polypeptide taught by Billing-Mendel (SEQ ID NO:36) in order to increase the immunogenicity of said polypeptide for therapeutic benefit of prostate cancer because cancer antigens are art recognized as being weakly immunogenic (immune escape). Thus, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to have produced an immunogenic composition and a method of inducing an immune response in a prostate cancer patient comprising administering said immunogenic composition, wherein said immunogenic composition comprises the polypeptide taught by Billing-Mendel (SEQ ID NO:36), which is a polypeptide comprising amino acid residues 367-375 of SEQ ID NO:113 and would have the claimed properties and an immunostimulant selected from MPL as taught by Hauser et al or saponin as taught by Ladd et al in order to increase the immunogenicity of said polypeptide for therapeutic benefit of prostate cancer.

13. The rejection of claims 19, 61 and 63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of U.S. Patent 6,329,505 in view of Hauser et al and Ladd et al is MAINTAINED.

The response filed 7/19/2004 has been carefully considered, but is deemed not to be persuasive. The response argues that the instant invention now requires that a polypeptide of the claimed invention comprises residues 367-375 of SEQ ID NO:113 corresponding to a specific T-cell epitope and the claims of U.S. Patent 6,329,505 make no reference to a polypeptide as instantly claimed (i.e., polypeptide comprising residues 367-375 of SEQ ID NO:113. In response to this argument claims 2-5 of U.S. Patent 6,329,505 recite that the polypeptide comprises at least a portion of a sequence having at least 90% or 95% identity to the entirety of SEQ ID NO:113 or comprises a sequence having at least 90% or 95% identity to a sequence selected form SEQ ID NOS:554, 558, 562 and 573,

which are all portions of SEQ ID NO:113. It is noted that SEQ ID NOS:554, 558, 562 and 573 do not contain residues 367-375 of SEQ ID NO:113, however, claims 3 and 4 of U.S. Patent 6,329,505 recite a polypeptide "comprising" and therefore, the claims encompass the entirety of SEQ ID NO:113. As discussed above because the polypeptides are identical (SEQ ID NO:113) they would have identical properties and it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce an immunogenic composition comprising the polypeptide of SEQ ID NO:113, (SEQ ID NO:113 comprises SEQ ID NOS:554, 558, 562, and 573; see page 25 of Office Action mailed 2/18/2004), and an immunostimulant selected from MPL as taught by Hauser et al or saponin as taught by Ladd et al in order to increase the immunogenicity of said polypeptide.

The Examiner acknowledges Applicant's filing of the Assignment documents for U.S. Patent 6,329,505, however, no terminal disclaimer has been filed to overcome the instant double-patenting rejection and therefore, the instant rejection is maintained.

14. The rejection of claims 19, 22, 61 and 63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-7 and 13 of U.S. Patent 6,261,562 in view of Hauser et al and Ladd et al is MAINTAINED.

The response filed 7/19/2004 has been carefully considered, but is deemed not to be persuasive. The response argues that the instant invention

now requires that a polypeptide of the claimed invention comprises residues 367-375 of SEQ ID NO:113 corresponding to a specific T-cell epitope and the claims of U.S. Patent 6,329,505 make no reference to a polypeptide as instantly claimed (i.e., polypeptide comprising residues 367-375 of SEQ ID NO:113. In response to these arguments, the claims in U.S. Patent 6,261,562 recite a polypeptide comprising SEQ ID NO:113, which is identical to SEQ ID NO:113 and therefore, is a polypeptide comprising residues 367-375 of SEQ ID NO:113 and would have the instantly claimed properties as discussed above. Further, the claims in U.S. Patent recite a method for stimulating an immune response with SEQ ID NO:113. Therefore, it would have been obvious to the skilled artisan at the time the invention was made to have produced an immunogenic composition and a method of inducing an immune response in as patient comprising administering said immunogenic composition, wherein said immunogenic composition comprises the polypeptide of SEQ ID NO:113, which comprises amino acid residues 367-375 of SEQ ID NO:113 and an immunostimulant selected from MPL as taught by Hauser et al or saponin as taught by Ladd et al in order to increase the immunogenicity of said polypeptide.

The Examiner acknowledges Applicant's filing of the Assignment documents for U.S. Patent 6,261,562, however, no terminal disclaimer has been filed to overcome the instant double-patenting rejection and therefore, the instant rejection is maintained.

New Grounds of Rejections

15. Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 is indefinite for reciting "predominantly Th1 type immune response" in claim 61. The phrase "predominantly Th1 type immune response" is not defined by the claims; the specification does not provide a standard for ascertaining the requisite degree or endpoint, and one of ordinary skill in the art would not reasonably be apprised of the metes and bounds of the invention. Is a predominant Th1 type immune response greater than 50% or 60% or 70% or 80% or 90% of the total immune response? Further, it is unclear what other types of immune responses (e.g., Th2) are encompassed by the phrase "predominantly Th1 type immune response".

16. Claims 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billing-Mendel et al (U.S. Patent 6,130,043, 5/2/1997, Ids filed 1/24/2003) in view of Mincheff et al (U.S. Patent 6,387,888 B1, 9/30/1998) and Salgaller et al (Prostate, 35(2):144-151, May 1998).

The claims are drawn to an immunogenic composition comprising an immunostimulant and an antigen-presenting cell that expresses a polypeptide that comprises the T-cell epitope of amino acid residues 367-375 of SEQ ID NO:113 and a method of stimulating an immune response in a patient comprising administering said composition.

Billing-Mendel teach a polypeptide of 242 amino acids (SEQ ID NO:36), which shares 100% amino acid identity with residues 299-529 of the instantly claimed SEQ ID NO:113 (see alignment attached to the back of this office action) and the polypeptide of SEQ ID NO:36 is encoded by the polynucleotide of SEQ ID NO:16 (see column 41, lines 18-25). Thus, Billing-Mendel et al teach a polypeptide (SEQ ID NO:36) that comprises residues 367-375 of SEQ ID NO:113. Since Billing-Mendel et al teaches a polypeptide (SEQ ID NO:36) of identical chemical structure with residues 299-529 of the instantly claimed SEQ ID NO:113, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Additionally, Billing-Mendel et al teach that SEQ ID NO:36, which is identical to residues 299-529 of SEQ ID NO:113 is expressed in prostate cancer tissue (see columns 40-41 and abstract). Billing-Mendel et al do not specifically teach an immunogenic composition comprising an immunostimulant and antigen-presenting cells that expresses a polypeptide comprising residues 367-375 of SEQ ID NO:113 or a method for stimulating an immune response in a patient comprising administering said immunogenic composition. These deficiencies are made up for in the teachings of Mincheff et al and Salgaller et al.

Mincheff et al teach antigen-presenting cells expressing a prostate cancer antigen following the introduction of DNA or RNA encoding said prostate cancer antigen (see columns 1-2). Mincheff et al also teach a method of treating prostate cancer patients, wherein dendritic cells are transfected with a nucleic

acid encoding a prostate cancer antigen and infused back into the prostate cancer patient where they stimulate autologous T-cells (see column 2).

Salgaller et al teach the administration of GM-CSF as a systemic adjuvant with dendritic cells pulsed with prostate cancer peptides, wherein infusion of the loaded dendritic cells in prostate cancer patients enhanced cellular immunity (see entire document, particularly page 145).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced an immunogenic composition comprising an immunostimulant and antigen-presenting cells that express SEQ ID NO:36 (i.e., a polypeptide comprising residues 367-375 of SEQ ID NO:113) as taught by Billing-Mendel and a method of stimulating an immune response in a patient comprising administering said immunogenic composition for therapeutic benefit of prostate cancer.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an immunogenic composition comprising an immunostimulant and antigen-presenting cells that express SEQ ID NO:36 (i.e., a polypeptide comprising residues 367-375 of SEQ ID NO:113) as taught by Billing-Mendel and a method of stimulating an immune response in a patient comprising administering said immunogenic composition for therapeutic benefit of prostate cancer in view of Billing-Mendel et al and Mincheff et al and Salgaller et al because Billing-Mendel et al teach a polypeptide expressed in prostate cancer tissues (prostate cancer antigen) that shares 100% amino acid identity with residues 299-529 of SEQ ID NO:113 and therefore is a

polypeptide comprising residues 367-375 of SEQ ID NO:113 and Mincheff et al teach a method of treating prostate cancer patients with dendritic cells transfected with a nucleic acid encoding a prostate cancer antigen and Salgaller et al teach the administration of dendritic cells with GM-CSF (immunostimulant) as a systemic adjuvant for the treatment of prostate cancer patients. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have transfected dendritic cells with the nucleic acid (SEQ ID NO:16) taught by Billing-Mendel, which encodes SEQ ID NO:36 (i.e., a polypeptide comprising residues 367-375 of SEQ ID NO:113) and administer said dendritic cells with GM-CSF as a systemic adjuvant for the treatment of prostate cancer patients. Thus, it would have been obvious to one skilled in the art to have produced an immunogenic composition comprising an immunostimulant and antigen-presenting cells that express SEQ ID NO:36 (i.e., a polypeptide comprising residues 367-375 of SEQ ID NO:113) as taught by Billing-Mendel and a method of stimulating an immune response in a patient comprising administering said immunogenic composition for therapeutic benefit of prostate cancer in view of Billing-Mendel et al and Mincheff et al and Salgaller et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusions

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER